

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/705,022 11/01/00 UMLAUF

S APF 37.20

POWDERJECT TECHNOLOGIES INC

HM22/1019

6511 DUMBARTON CIRCLE
FREMONT CA 94555

EXAMINER

WHITEMAN, B

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.		Applicant(s)	
	09/705,022		UMLAUF, SCOTT	
	Examiner		Art Unit	
	Brian Whiteman		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-41 are pending and under consideration in the pending application

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, drawn to polynucleotide comprising a first promoter derived from a gene encoding a co-stimulatory molecule and a first sequence encoding at least one antigen wherein said first sequence is operably linked to said first promoter, pharmaceutical compositions comprising polynucleotides and cytokines, methods of eliciting an immune response via polynucleotides, classifiable in class 514, subclass 44, class 536, subclass 23.1.
- II. Claims 26, 29, 32, and 35-37, drawn to a vaccine composition comprising (a) an expression vector comprising a polynucleotide encoding at least one antigen; and (b) at least one cytokine selected from the group consisting of CD40 ligand (CD40L), tumor-necrosis factor-related activation-induced cytokine (TRANCE), and Flt3 ligand (flt-3L), classifiable in class 514, subclass 44.
- III. Claims 27, 30, 33, 38-39, drawn to a vaccine composition comprising (a) at least one peptide antigen; and (b) an expression vector comprising a polynucleotide encoding at least one cytokine selected from the group consisting of CD40 ligand (CD40L), tumor-necrosis factor-related activation-induced cytokine (TRANCE), and Flt3 ligand (flt-3L), classifiable in class 514, subclass 44, class 424, subclass 184.1.

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- IV. Claims 28, 31, 34, 40 and 41, drawn to a vaccine composition comprising (a) at least one peptide antigen; and (b) at least one cytokine selected from the group consisting of CD40 ligand (CD40L), tumor-necrosis factor-related activation-induced cytokine (TRANCE), and Flt3 ligand (flt-3L), classifiable in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct because the polynucleotide of invention I is distinct in chemical structure and function, as well as therapeutic effect, from the vaccine composition of invention II-IV. Additionally, the polynucleotides and peptide antigens can be used for materially different processes. Furthermore, the methods of eliciting an immune response via polynucleotides in invention I requires a different immune function within a mammal to elicit a response, and has a different mechanism of action, as compared to the vaccine composition of invention II-IV. Specifically, invention I requires a promoter derived from a gene encoding a co-stimulatory molecule and inventions II-IV do not require the co-stimulatory promoter. Furthermore, Invention II-IV can use any type of vector and are structurally distinct compared to Invention I. In addition, each class and subclass requires a separate search status on the basis of the classification system, which recites an enormous number of potential and patentably distinct inventions within each class and subclass.

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Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I-IV constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, Group II is distinct from Group III because Group II refers to a vaccine comprising an expression vector comprising a polynucleotide encoding at least one antigen; and at least one cytokine; Group II is a vaccine composition comprising at least one peptide antigen; and an expression vector comprising a polynucleotide encoding at least one cytokine; Group III is a vaccine composition comprising at least one peptide antigen; and at least one cytokine. Each Group requires different material for production of a vaccine composition and each group has a different mode of operation and effect. Thus, inventions I-IV are distinct.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Groups II-IV, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
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DAVE T. NGUYEN
PRIMARY EXAMINER